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REMARKS

Applicant has amended claims 1, 21, 23 and 24. Care had been taken to avoid the introduction of new matter. Claims 1-11 and 21-24 are presently pending in the application.

The Office Action rejected claims 1, 2-11 and 21-24 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement, and further rejected claims 1, 2-11 and 21-24 under 35 U.S.C. 112, first paragraph, as allegedly failing, in particular, to provide enablement for only a lactide polymer or only a lactide copolymer. Regarding these rejections, Applicant respectfully disagrees with the above rejections and submits that, even before the entering of the current amendment, the claims were sufficiently definite and were adequately supported to fully meet the requirements of the relevant patent statutes. In particular, for example, the language of claim 1 clearly was not limited to "either" a poly-lactide polymer or a copolymer of two or more lactides, and, furthermore, any permutation of these items was supported in the as-filed specification. In an effort to expedite the prosecution of the present application, however, Applicant has amended the current claims, not so much as to overcome the rejections but rather to further define one or more aspects of the present invention. For example, claim 1 has been amended based upon support which can be found, for example, in one or more of (a) the current Summary and Detailed Description and (b) U.S. Patent No. 6,531,146 which is incorporated by reference into the specification of the subject patent application. Furthermore, the current amendments address paragraphs 9-12 of pages 4 and 5 of the Office Action. In view of the preceding, the Examiner is requested to reconsider and withdraw the rejections under 35 U.S.C. § 112.

The Office Action also rejected claims 1, 4-11 and 21 on prior-art. Regarding this prior-art rejection, claims 1, 4-11 and 21 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Totakura et al. (U.S. Patent No. 5,795,584). Applicants respectfully disagree with this rejection.

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Independent claim 1 has been amended as set forth above. Applicant respectfully traverses this rejection, as it relates, in particular, to the claims even before the present amendment but especially after the entering of this amendment. Applicant submits that the present claims are not obvious over Totakura et al. In particular, Applicant submits that the reference, alone or in combination with any other prior-art reference of record, does not provide the required suggestion or motivation to render any of the present claims obvious under 35 U.S.C. § 103(a).

Regarding the outstanding rejection, it is well established that a claim can be rejected on obviousness grounds only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior-art reference or combination of prior-art references. Thus, for a rejection under 35 U.S.C. 103(a) to be proper, every limitation recited in a claim, which is rejected as being obvious in view of one or more prior-art references, must be disclosed or taught in that prior-art reference or references. In the instant case, Applicant respectfully submits that the cited reference neither discloses nor suggests each and every element that is recited in the rejected claims. Accordingly, as set forth herein, the outstanding rejection under 35 U.S.C. § 103(a) is improper and should be withdrawn.

Applying the above standard, the Totakura et al. reference does not disclose or suggest a method for promoting healing of damaged tissue after an open heart surgery, the method including, among other things, providing a substantially planar healing membrane which is (a) substantially-smooth on at least one side; (b) substantially uniform in composition; (c) about 10 microns to about 300 microns in thickness; (d) non-porous; (e) constructed from a resorbable polymer base material consisting essentially of a material selected from the group consisting of a poly-lactide polymer and a copolymer of two or more lactides; and (f) adapted to be resorbed into the mammalian body within a period of approximately 18 to 24 months from an initial implantation of the healing membrane into the mammalian body; and placing the healing

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membrane adjacent to an opening in pericardial tissue of a patient so that the pericardial tissue surrounding the opening can regenerate over the healing membrane, as recited in independent, amended claim 1.

Applicant is not seeking claim coverage for every resorbable film in existence, but rather for a particular membrane having a particular composition and construction. More particularly, the currently claimed membranes comprise smooth, uniform, non-porous, layers consisting essentially of poly-lactides and copolymers of multiple lactides. As for the Totakura et al. patent, it is described in the Background section of U.S. Patent No. 6,531,146, which is incorporated into the subject application by reference, as being formed of a bioabsorbable polymer that is copolymerized with a suitable carbonate. The Totakura et al. patent involves relatively complex chemical formulas and/or reactions resulting in particular structures to be used as surgical adhesion barriers.

Importantly, the Totakura et al. structure would appear to be limited to always being formed of carbonates, which, incidentally, are combined with bioabsorbable polymer forming materials (e.g., lactides). A composition does not "consist essentially of" a lactide or copolymer of lactides (cf. presently pending claims 1 and 28) simply because it is formed from a copolymer that may contain a lactide.

This disclosure of Totakura et al. would not have made it obvious to have fabricated PLA membranes of the shape, size, porosity and fluid permeability as claimed in the instant application. As earlier alluded, Applicant does not assert claim to the broad concept of using polylactide polymers and co-polymers in medical devices. One of the points of novelty of the present invention lies, inter alia, in the use of poly-lactide polymers in micro-membrane form. Specifically, the Applicant claims a substantially planar membrane comprising, among other things, a single layer of non-porous, resorbable polymer base material having at least one

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substantially smooth side. The thickness of the single layer is between about 10 microns and 300 microns.

The micromembranes disclosed by Applicant are designed to be implanted as barriers between a healing post-surgical site and adjacent surrounding tissue. The compositions formed into smooth, non-porous structures provide Applicant's membranes with numerous advantages over prior art surgical adhesion barriers. Namely, as discussed in the present application, the claimed membranes can achieve one or more of, for example: attenuate or eliminate interactions of the tissues, reduce tissue turbulence, enhance tissue guidance, and minimize scar formation. In addition, the smooth compositions may facilitate movement of the dura and local tissues across the area, thus reducing frictional rubbing and wearing which may induce scar tissue formation. Moreover, the compositions, in addition to reducing interactions as discussed in the present application, can be formed of relatively simple chemical formulas and/or reactions.

In view of the foregoing amendments and remarks, it is respectfully submitted that independent, amended claim 1, and the claims dependent thereon, are neither anticipated nor rendered obvious by Totakura et al., taken separately or together with any other reference of record. Applicant accordingly requests that the rejection based on Totakura et al. be reconsidered and withdrawn.

Allowance of all presently pending claims is respectfully requested. If a telephone conversation with Applicant's attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicant's attorney at the below number.

Respectfully submitted,


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